

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1616
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JAN 18 2001
TECH CENTER 1600/2900

In re the application of:

Fischetti et al.

Serial No. 09/960,472

Group: 1616

Filed: September 24, 2001

Examiner: Raj Bawa

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

PROPRIETARY INFORMATION DISCLOSURE STATEMENT

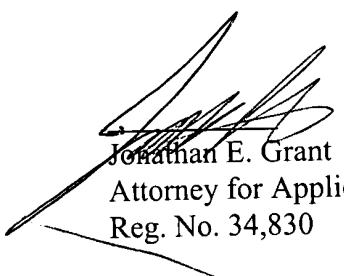
Sir:

The attached is a proprietary list of patents and patent applications filed by the inventors or the owners of the present invention. Most of the patent applications will not issue before the issue date of the above listed serial number. It is therefore requested that those patent applications on the attached list not issued prior to the issuance of the above listed patent be redacted.

Applicant provides the following summaries of the enclosed prior art, along with a Form PTO-1449, all of which are enclosed.

The statement is submitted under the provisions of 37 CFR 1.56 and 1.97(b)(1).

Respectfully submitted,


Jonathan E. Grant
Attorney for Applicant
Reg. No. 34,830

2002 HGBREH1 00000093 09960472

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Jonathan E. Grant
Grant Patent Services
2120 L Street, N.W.
Suite 210
Washington, D.C. 20037
(301) 603-9071

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LIST OF NEW HORIZON PATENTS AND PATENT APPLICATIONS

Patent/Application No.	Country	Filing Date	Issue Date	Inventors	Title
Pat. No. 5,604,109	U.S.A.	09-13-94	02-18-97	Fischetti	A Method for Exposing Group A Streptococci Antigens and an Improved Diagnostic Test for the Identification of Group Streptococcus.
Pat. No. 5,997,862 App No.09/962,523	U.S.A.	10-31-97	12-7-99	Fischetti Loomis	Therapeutic treatment of Group A Streptococcal Infections
Pat. No. 6,017,528 App No. 09/257,025 (Cert. of Correction)	U.S.A.	02-25-99	01-25-00	Fischetti Loomis	Therapeutic Treatment of Group A Streptococcal Infections
Pat. No. 5,985,271 No.09/257,026 (Cert. of Correction)	U.S.A.	02-25-99	11-16-99	Fischetti Loomis	Prophylactic and Therapeutic Treatment of App of Group A Streptococcal Infections
Pat. No. 6,506,954 App.No. 09/395,636 (Cert. of Correction)	U.S.A.	09-14-99	05-02-00	Fischetti Loomis	Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Various Illnesses
Pat. No. 6,238,661 App. No. 09/497,495	U.S.A.	04-18-00	05-29-01	Fischetti Loomis	Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses
Pat. No. 6,264,945 App. No.09/482,992	U.S.A.	01-14-00	07-24-01	Fischetti Loomis	Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic

Treatment of Bacterial Infections

Topical Treatment of Streptococcal Infections

Pat. No. 6,056,955
App. No. 09/395,637

U.S.A. 09-14-99

05-02-00

Fischetti
Loomis

The Use of Phage Associated Lytic Enzymes
For the Rapid Detection of Bacterial

App. No. 09/654,484

U.S.A. 09-01-00

Trudil

A Composition for Treatment of A
Bacterial Infection of An Upper
Respiratory Tract

App. No. 09/654,483

U.S.A. 09-01-00

Fischetti
Loomis

Use of Phage Associated Lytic Enzymes
For Treating Bacterial Infections of the
Digestive Tract

Pat. No. 6,254,866
App. No. 09/653,690

U.S.A. 09-01-00

07-03-01

Fischetti
Loomis

A Composition for Treatment of a Bacterial
Infection of the Digestive Tract

App. No. 09/654,482

U.S.A. 09-01-00

Fischetti
Loomis

Compositions Incorporating Bacterial
Phage Associated Lysing Enzymes For
Treating Dermatological Infections

Pat. No. 6,277,399
App. No. 09/671,882

U.S.A. 09-28-00

08-21-01

Fischetti
Loomis

A Composition for Treatment of Vaginal
Bacterial Infections

App. No. 09/671,881

U.S.A. 09-28-00

Fischetti
Loomis

A Composition for Treatment of An
Ocular Bacterial Infection

.App. No. 09/671,880

U.S.A. 09-28-00

Fischetti
Loomis

Bacterial Phage Associated Lysing

Pat. No. 6,248,324

U.S.A. 09-28-00

06-19-01

Fischetti

App. No. 09/671,879

Loomis
Enzymes for Treating Dermatological Infections

App. No. 09/671,878

U.S.A. 09-28-00

Fischetti
Loomis
The Use of Bacterial Phage Associated
Lytic Enzymes for Treating
Dermatological Infections

App. No. 09/671,991

U.S.A. 09-28-00

Fischetti
Loomis
A Composition for Treating Dental
Caries Caused by Streptococcus Mutans

Pat. No. 6,335,012
App. No. 09/671,992

U.S.A. 09-28-00 01-01-02

Fischetti
Loomis
A Method for Treating Dental Caries
Caused by Streptococcus Mutans

NOTE: THE USPTO PRINTED THE WRONG TITLE AND THE WRONG CLAIMS

Pat. No. 6,326,002
App. No. 09/671,990

U.S.A. 09-28-00 12-04-01

Fischetti
Loomis
The Use of Bacterial Phage Associated
Lysing Enzymes for Treating Bacterial
Infections of the Upper Respiratory
System

App. No. 09/704,148

U.S.A. 11-02-00

Fischetti
Loomis
Trudil
The Use of Bacterial Phage Associated
Lytic Enzymes to Prevent Food
Poisoning

App. No. 09/560,650

U.S.A. 04-28-00

Fischetti
Loomis
The Use of Bacterial Phage
Associated Lysing Enzymes for the
Prophylactic and Therapeutic
Treatment of Various Illnesses

App. No. 09/752,731

U.S.A. 01-03-01

Fischetti
Loomis
The Parental Use of Bacterial Phage
Associated Lysing Enzymes For The
Lysing Enzymes for the Therapeutic

App. No. 09/932,460	U.S.A.	07-13-01	Fischetti Loomis	Treatment of Bacterial Infections
				The Use of Bacterial Phage Associated Lysing Enzymes for Treating Various Illnesses
Prov. No. 60/324,089	U.S.A.	09-24-01	Fischetti Loomis	The Use of Bacterial Shuffled and Chimeric Phage Associated Lytic Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections caused By <i>Streptococcus Pneumoniae</i>
App. No. 09/960,472	U.S.A.	09-24-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes for the Prophylactic and Therapeutic Treatment of Colonization and Infections Caused by <i>Streptococcus pneumoniae</i>
App. No. 09/908,737	U.S.A.	07-19-01	Fischetti Loomis	Parenteral Use of Bacterial Phage Associated Lysing Enzymes for the Therapeutic Treatment of Bacterial Infections
App. No. 09/910,940	U.S.A.	07-13-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lytic Enzymes to Prevent Food Poisoning
App. No. 09/844,435	U.S.A.	04-30-01	Fischetti Loomis	The Use of Bacterial Phage Associated Lysing Enzymes For

Treating Various Illnesses

App. No. 09/846,688 U.S.A. 05-02-01

Fischetti
Loomis

The Use of Bacterial Phage
Associated Lysing Proteins for the
Prophylactic and Therapeutic
Treatment of Various Illnesses

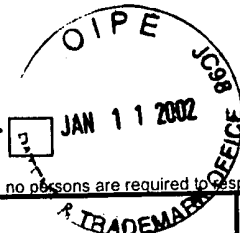
PCT/US99/04063 PCT 02-25-99

Fischetti
Loomis

A Means for the Prophylactic and
Therapeutic Treatment of
Streptococcal Infections

N/A INDIA
99909595.3 EPO
2000-600679 JAPAN
2001126302 RUSSIAN FEDERATION
not yet filed POLAND
P19917152-0 BRAZIL
514260 NEW ZEALAND
2001-700898 NORTH KOREA
200105279-4 SINGAPORE
N/A CANADA
145087 ISRAEL
28767/99 AUSTRALIA
N/A CHINA

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

5

Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

1618

BAWA, R.

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		6,264,945		Fischetti et al.	07-24-2001	
		6,254,866		Fischetti et al.	07-03-2001	
		6,248,324		Fischetti et al.	06-19-2001	
		6,238,661		Fischetti et al.	05-29-2001	
		6,056,955		Fischetti et al.	05-02-2000	
		6,056,954		Fischetti et al.	05-02-2000	
		6,017,528		Fischetti et al.	01-25-2000	
		5,997,862		Fischetti et al.	12-07-1999	
		5,985,271		Fischetti et al.	11-06-1999	
		5,688,501		Merril et al.	11-18-1997	
		4,957,686		Norris	09-18-1990	
		5,604,109		Fischetti et al.	02-18-1997	
		5,882,631		Suga et al.	03-16-1999	
		5,741,487		Asai et al.	04-21-1998	
		6,113,887		Mori et al.	09-05-2000	
		4,122,158		Schmitt	10-24-1978	
		3,983,209		Schmitt	09-28-1976	
		6,113,887		Mori et al.	09-05-2000	
		4,885,163		Shaar et al.	12-05-1989	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			WO 97 02351 A		CIBA GEIGY AG, et al.	01-23-1997		
			WO 96 07329 A		UNIV. MARYLAND	03-14-1996		
			EP 0 510 907 A		AGRICULTURAL & FOOD RES	10-28-1992		
			WO 99 04809 A		AMBI INC	02-04-1999		

Examiner
Signature

Date

Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	
				Group Art Unit	1619
				Examiner Name	BAWA
				Attorney Docket Number	
Sheet	2	of	5		

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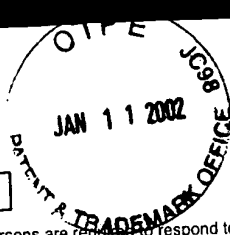
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		Filing Date	
		First Named Inventor	
		Group Art Unit	1619
		Examiner Name	BAWA
		Attorney Docket Number	
Sheet	3	of	5

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		Reisenger, et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L Genes" <i>Fems Microbiol Letter.</i> 164(1) p.159-167
		Sheehan MM, et al. (1997) "The lytic enzyme of the Pneumococcal Phage Dp-1: a chimeric lysis of intergeneric origin." <i>Mol. Microbiol.</i> 25(4) p. 717-725
		Young et al. (2000) "Phages will out: strategies of host cell lysis." <i>Trends in Microbiology.</i> 8(4) p. 120-127
		Garcia et al.(1997) "The Pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microb. Drug Resist.</i> 3(2): p. 199-211
		Sheehan MM, et al., (1997) "The Lytic Enzyme of the Pneumococcal Phage Dp-1: a Chimeric Lysin of Intergeneric Origin" <i>Mol. Microbiol.</i> 25(4) p. 717-25
		Garcia P, et al. (1997) "Bacteriophages of Streptococcus pneumoniae: a molecular approach" <i>Microb. Drug Resist.</i> 3(20) 165-76.
		Sheehan, MM, et al.(1996) "Analysis of the catalytic domain of the lysin of the lactococcal bacteriophage Tuc2009 by chimeric gene assembling." <i>FEMS Microbiol.Lett.</i> 14(1): p. 23-28.
		Sanz, JM, et al. (1996) "Construction of a multifunctional pneumococcal murein hydrolase by module assembly." <i>Eur. J. Biochem.</i> 235(3):601-5
		Lopez R, et al. (1995) "Architecture and Domain Interchange of the Pneumococcal Cell Wall Lytic Enzymes" <i>Dev. Biol. Stand.</i> 85 p. 273-81.

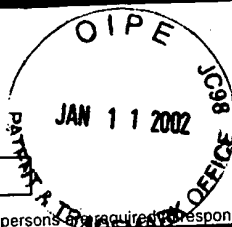
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		Filing Date	
		First Named Inventor	
		Group Art Unit	1619
		Examiner Name	BAWA
Sheet	4	of	5
		Attorney Docket Number	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Croux, et al.(1993) "Interchange of Functional Domains Switches Enzymes Specificity: Contstruction of a chimeric pneumococcal-clostridial cell wall lytic enzyme." <i>Mol. Microbiology</i> . 9(5) p. 1019-25.	
		Diaz, E. et al. (1990) "Chimeric phage-bacterial enzymes: a clue to the modular evolution of genes. <i>PNAS</i> . 87(20) p. 8125-9.	
		Diaz, E. et al.(1990) "Chimeric pneumoccal cell wall lytic enzymes reveal important physiological and evolutionary traits." <i>J. Biol. Chem.</i> 266(9) p. 5464-71.	
		Lopez, et al. (1997) "The pneumococcal cell wall degrading enzymes: A modular design to create new lysins?" <i>Microbiological Drug Resistance</i> , 3(2) p. 199-211.	
		Loessner, et al. (1999) "Evidence for a holin-like protein gene fully embedded out of frame in the endolysin gene of <i>Staphylococcus aureus</i> Bacteriophage." (1999) <i>Journal of Bacteriology</i> , 181(15) p. 4452-4460.	
		Witte, A et al. (1998) "Characterization of Escherichia coli lysis using a family of chimeric E-L genes." <i>FEMS Microbiol. Lett.</i> , 164(1), p. 159-167	
		Martin, Ana C et al (1998): "Functional analysis of the two-gene lysis system of the pneumococcal phage Cp-1 in homologous and heterologous host cells." <i>Journal of Microbiology</i> 180(2), p. 210-217	
		Oki Masaya et al. (1997) "Functional and structural features of the holin HOL protein of the Lactobacillus plantarum phage phi-gle: Analysis in Escherichia coli system." <i>Gene (AMSTERDAM)</i> 197(1-2) p 137-145.	

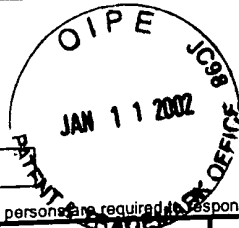
Examiner Signature	Date Considered
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¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	
		Filing Date	
		First Named Inventor	
		Group Art Unit	1619
		Examiner Name	BAWA
Sheet 5 of 5		Attorney Docket Number	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
		Young, Ry et al. (2000) "Phages will out: strategies of host cell lysis." <i>Trends in Microbiology</i> , 8(3) p 120-127.	
		Nelson, et al. (2001) "Prevention and elimination of upper respiratory colonization of mice by Group A Streptococci by using a bacteriophage lytic enzyme." <i>PNAS</i> . 98 (7) p. 4107-4112	
		Garcia, et al. (1987) "Purification and biochemical characterization of the pneumococcal bacteriophage Cp-1 lysin." <i>Journal of Virology</i> 61(8) p. 2573 - 2580.	
		Loessner, et al. (1996) "Modified Listeria bacteriophage lysin genes (ply) allow efficient overexpression and one-step purification of biochemically active fusion proteins." <i>Applied and Environmental Microbiology</i> . 62(8) p. 3057-3060	

Examiner Signature		Date Considered	
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† Unique citation designation number. ‡ Applicant is to place a check mark here if English language Translation is attached.

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